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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

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**Office Action Summary**

Application No.

09/742,454

Applicant(s)

WILEY, STEVEN R.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 October 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 39 and 46-90 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39 and 46-90 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. The amendment filed 10/3/2002 (paper no. 13) is acknowledged and entered into the record. Accordingly, claims 1-3 and 6-23 have been canceled, claims 46-90 have been newly added. Therefore, claims 39 and 46-90 are pending and examined on the record.

#### ***Information Disclosure Statement***

2. The Information Disclosure Statement filed 10/23/2002 (paper no. 14) is acknowledged and considered. A signed copy of the IDS is attached hereto.

#### ***Claim Rejections Maintained- 35 USC § 112, 2<sup>nd</sup> paragraph***

3. The rejection of claims 1-3, 6, 8-23 and 39 under 35 USC 112, 2<sup>nd</sup> paragraph as being indefinite is rendered moot because of the cancellation of the claims. However, this rejection can now be applied to newly added claims 72-90. Applicant argues that the claims must be read in light of the specification and that the terms are clearly and adequately defined and discussed in the specification. Applicant's arguments have been carefully considered but are not found persuasive for the following reasons. The terms "fragment" and "variants" as it applies to phrases such as "a soluble fragment...of SEQ ID No: 2" or "a variant that is at least 80%..." are understood to mean that the "fragment" is a portion of the extracellular domain of SEQ ID No: 2 or that the "variant" is a sequence that has substantial (i.e. 80% identity) homology to SEQ ID No: 2, however, one of skill in the art would not be able to fully understand which portions or "fragments"

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or which variants are intended to be encompassed. SEQ ID No: 2 represents the extracellular portion of TWEAK-R, of which any part, ranging from 1-78 amino acids could be envisioned as part of the invention as it applies to the term "fragment". Any portion within this span of amino acids could be envisions of which there are numerous possibilities. "Variants" could encompass any protein that comprises the sequences of SEQ ID No: 2. Because these terms fail to particularly point out and distinctly claim the invention so as to teach one of skill in the art what the terms actually mean, and because the specification has not provided enough description as to how to interpret the terms, the metes and bounds of the term cannot be adequately determined.

***Claim Rejections Maintained- 35 USC § 112, 1<sup>st</sup> paragraph***

4. The rejection of claims 1,6,8,11, and 12 under 35 USC 112, 1<sup>st</sup> paragraph as lacking an enabling disclosure is rendered moot in light of the cancellation of claims. However, the rejection is maintained for claim 39 and can be applied to newly added claims 58-90. Applicant argues that the instant specification provides detail description to one of skill in the art as to the potential types of receptor antagonists, the test for screening these potential receptor antagonists, and methods of using these antagonists to inhibit angiogenesis. These antagonist include for example antibodies, peptide fragments, anti-sense molecules, ribozymes, and triple helical molecules. The applicant's arguments have been carefully considered but are not found persuasive for the following reasons. The specification has not taught what the actual fragments, antagonists, ribozymes, antisense molecules, or triple helical molecules are, so as to

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practice the invention as claimed. One of skill would be forced into undue experimentation to test an assortment of potential antagonists as encompassed by the claims. Although the specification has provided a general guideline to screen and use the potential antagonists for a method of inhibiting angiogenesis, the fact that no specific antagonists, other than antibodies that specifically bind to the TWEAK receptor and the Fc polypeptide fusion protein comprising amino acids 28-79 of SEQ ID No: 7, were taught, one of skill would not know where to begin looking for antagonist that fulfill the embodiments of the claim. Since the antagonists are critical for the success of the method and because not all antagonists work in the same manner, it would require undue experimentation for one of skill to practice the invention. The applicant points to specific pages in the specification which allegedly provide detailed disclosures of other embodied antagonists such as for example inhibitory anti-sense, ribozymes, and triple helical molecules. However, upon consideration of the specifically disclosed embodiments, the antagonists described do not provide one of skill in the art with any specific indication of what the actual antagonists are. Any anti-sense, ribozyme, or triple helical molecule is potentially encompassed by the claim. Therefore, the specification has only provided a disclosure for antibodies that bind to the extracellular domain of TWEAK receptor and a fusion protein comprising an Fc and a polypeptide comprising amino acids 28-79 of SEQ ID No: 7.

***Claim Rejections - 35 USC § 112 § 112, 1<sup>st</sup> paragraph***

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5. The rejection of claims 1-3, 6, 8-23, and 39 under 35 USC 112, 1<sup>st</sup> paragraph as lacking proper written description is rendered moot in light of the cancellation of claims or due to the amendment of claim language (claim 39). However, the rejection is **maintained** and is applied to newly added claims 72-90 to the extent that the claims now read on fragment and variants of SEQ ID No: 2. Applicant argues that the specification has provided structural and functional descriptions for each molecule recited. Further, the applicant argues that since the full length sequence of Tweak receptor extracellular domain is disclosed, one of skill in the art would be able to envision any fragment or variant thereof with some precision. The arguments have been carefully considered but are not found persuasive. Although the specification has disclosed SEQ ID No: 2 and or 7, one of skill in the art could understand which fragments and variants possibly derive from the disclosed sequences. However, the skilled artisan is unable to ascertain whether specific variants or fragments are specifically disclosed in the instant application because no specific variants or fragments are provided in the disclosure. Despite the fact that the entire sequence of the extracellular domain of TWEAK receptor has been provided, the specific amino acid sequences that make up the variants or fragment have not been specifically disclosed. As such one of skill would not be able to ascertain whether the applicant of the instant invention was in possession of specific variants or fragments of SEQ ID No: 2. Given the fact that the sequence for the entire extracellular domain of TWEAK receptor has been provided, fragments or variants of this sequence cannot be precisely envisioned, because the actual sequence of the individual fragments or variants have not been

disclosed. Therefore, the written description has only set forth SEQ ID No:2, fragments or variants of SEQ ID No: 2 cannot be envisioned and therefore do not meet the requirements for written description.

### ***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

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308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Christopher Yaen  
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December 12, 2002

